IN THE COURT OF APPEALS OF THE STATE OF MISSISSIPPI

NO. 2012-CA-01507-COA

BARBARA ANN THOMPSON BOLTON APPELLANT

VS.

ROGER WEINER, M.D. APPELLEE

MEMORANDUM IN SUPPORT OF MOTION FOR RECONSIDERATION

STATEMENT OF FACT

The facts upon which Plaintiff/Appellant's reconsideration are based are stated in her Motion and Argument.

INTRODUCTION

The majority opinion in this case based its decision on two assumptions:

(1) that since there is no conclusive evidence that amiodarone causes optic neuropathy, the doctor was relieved of the duty imposed by the FDA of the warning contained and directions for ophthalmological examinations also contained therein; and

(2) further an internist specializing in pulmonology is not qualified to render an opinion as to whether a cardiologist should follow the directions of the package insert.

ARGUMENT

THE PROOF OF CAUSAL RELATIONSHIP NECESSARY TO REQUIRE THE FOLLOWING OF A PACKAGE INSERT

As stated in her Motion, Defendant/Appellee was and is a medical doctor specializing in cardiology and Plaintiff/Appellant engaged his services for treatment, which he embarked upon. In the course of his treatment he prescribed the drug amiodarone manufactured by Wyeth.

The Food and Drug Administration, an agency of the United States government, after review of studies of the effects and side effects of the drug required that Wyeth, in its package insert, include the following:

"**Loss of Vision**

> Cases of optic neuropathy and/or optic neuritis, usually resulting in visual impairment, have been reported in patients treated with amiodarone. In some cases, visual impairment has progressed to permanent blindness. Optic neuropathy and/or neuritis may occur at any time following initiation of therapy. A causal relationship to the drug has not been clearly established. If symptoms of visual impairment appear, such as changes in visual acuity and decreases in peripheral vision, prompt ophthalmic examination is recommended. Appearance of optic neuropathy and/or neuritis calls for re-evaluation of Cordarone therapy. The risks and complications of antiarrhythmic therapy with Cordarone must be weighed against its benefits in patients whose lives are threatened by cardiac arrhythmias. Regular ophthalmic examination, including fundoscopy and slit-lamp examination, is recommended during administration of Cordarone. (See "**ADVERSE REACTIONS**")

PRECAUTIONS
Impairment of Vision
Optic Neuropathy and/or Neuritis
Cases of optic neuropathy and optic neuritis have been reported (see "WARNINGS").
Corneal Microdeposits
Corneal microdeposits appear in the majority of adults treated with Cordarone. They are usually discernible only by slit-lamp examination, but give rise to symptoms such as visual helps or blurred vision in as many as 10% of patients. Corneal microdeposits are reversible upon reduction of dose or termination of treatment. Asmptomatic microdeposits alone are not a reason to reduce dose or discontinue treatment (see "**ADVERSE REACTIONS**").
Neurologic
Chronic administration of oral amiodarone in rare instances may lead to the development of peripheral neuropathy that may resolve when amiodarone is discontinued, but this resolution has been slow and incomplete."

The query which Plaintiff/Appellant would pose to the Court is what weight is to be given to the conclusion reached by the FDA as to appropriate warnings and directions after its exhaustive study of a drug?

The query was answered by the Oregon Court of Appeals in the case of *Axen vs. American Home Products Corporation*, 974 Pacific 2d 224 (1999). This Court in that case stated:

> "We conclude that the trial court's rulings correctly embodied the principles set forth in *Gattman v. Favro*, 306 Or. 11, 15 n. 3, 757 P.2d 402 (1988), on the use of governmental rules to establish a standard of care in a negligence action.
>
> In that case, the court explained:
>
> > "Strictly speaking, the doctrine of 'negligence per se' does not create a cause of action. Rather, it refers to a standard of care that a law imposes within a cause of action for negligence. As [the court] stated in *Shahtout v. Emco Garbage Co.*, 298 Or. 598, 601, 695 P.2d 897 (1985):

"'When a plaintiff (or a defendant seeking to prove negligence on plaintiff's part) invokes a governmental rule in support of that theory, the question is whether the rule, though it was not itself meant to create a civil claim, nevertheless so fixes the legal standard of conduct that there is no question of due care left for a factfinder to determine; in other words, that noncompliance with the rule is negligence as a matter of law. This court long has held that violations of statutory safety rules by themselves provide the element of negligence with respect to those risks that the rules are meant to prevent, at least unless the violator shows that his conduct in fact did not violate the rule under the circumstances. *Barnum v. Williams*, 264 Or. 71, 504 P.2d 122 (1972); *Peterson v. Standard Oil Co.*, 55 Or. 511, 106 P. 337 (1910).' "

Interestingly, the *Axen* case dealt with optic neuropathy caused by amiodarone. Citing 21 CFR §314.80 and 314.81, the Court concluded that the findings of the FDA regarding the failure to adhere to the FDA's prior warnings and instructions constituted negligence per se.

Of course, in this case at bar, Plaintiff/Appellant only seeks to have the Court declare that failure to adhere to the directions of the FDA to be a question of fact as opposed to being of no effect.

Plaintiff/Appellant would again call the Court's attention to the case of *Hermes vs. Pfizer*, 848 Fed.2d 66 (Miss. 1988). The Court in interpreting Mississippi law held that the manufacturer had a duty to warn of the **possible** harmful effect of the drug; and, therefore, sustained a judgment for the Plaintiff.

It is recognized in both of these cases that the Defendant was the manufacturer.

However, of what value are warnings and the instructions required of the manufacturer by the FDA, if those warnings and instructions are not conveyed to the user of the drug?

It is submitted that the FDA was not created by Congress for any purpose other than to protect users of the drugs effected by the FDA and for the intent of Congress to have any effect, the user-consumer must be made aware of the warnings and instructions.

The only party that can be relied upon to convey the warnings and instructions of the drugs is the physician who has also been called the learned intermediary. Therefore, when he defaults on this duty, a cause of action arises or at the very least, a question of fact is created.

QUALIFICATION OF EXPERT

Plaintiff/Appellant's expert was an internist who specialized in pulmonology. The Defendant/Appellee is a cardiologist. However, Plaintiff/Appellant's expert did not limit his opinion in any way to any particular specialty, since the following of instructions and warnings given by the government of the United States of America is not limited to any specialty. Therefore, the opinion of any medical doctor concerning the necessity of following the warnings and instructions contained in the manufacturer's package insert as reflected in the *Physician's Desk Reference* (PDR) is authoritative in establishing the minimum standard of conduct.

Plaintiff/Appellant's specialty has nothing to do with it.

A cardiologist could well render an expert opinion as to whether a pulmonologist deviated from the minimum standard of care in failing to advise his patient of the instructions and warnings concerning a drug given for a lung condition.

CONCLUSION

It is submitted that the Food and Drug Administration, created by Congress to protect American citizens from the dangers of both food and drugs. With regard to the drugs, the FDA under its mandate, scrutinizes each drug and requires the manufacturer to place warnings and instructions on a package insert to warn and instruct users of the proper use and potential dangers in its use. It is submitted that neither the industry nor the United States government would countenance a frivolous warning or instructions. Therefore, it is submitted that the warnings that the FDA required the manufacturer to place in package insert (as also printed in the *Physicians' Desk Reference*) are meant to be followed and failure to do so constitutes negligence or a question of negligence. Of course, very few users have the opportunity to read the package insert; and, therefore, it is the physician who must have knowledge of it and must warn and instruct his patient in its use.

Therefore, it is submitted that the violation of the Food and Drug Administration directives raise – at the very least – a question of fact.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I, Allan D. Shackelford, attorney for Appellant, do hereby certify that I have this day mailed, postage prepaid by United States mail, a true and correct copy of the above and foregoing Memorandum in Support of Motion for Reconsideration of Barbara Ann Thompson Bolton to:

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THIS, the 10th day of July, 2014.

ALLAN D. SHACKELFORD